No. 15-105

# In The Supreme Court of the United States

LITTLE SISTERS OF THE POOR
HOME FOR THE AGED, Denver, Colorado, et al.,

*Petitioners,*

v.

SYLVIA BURWELL, Secretary of
Health and Human Services, et al.,

*Respondents.*

**On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Tenth Circuit**

## *AMICUS CURIAE* BRIEF OF ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS, CHRISTIAN MEDICAL ASSOCIATION, CATHOLIC MEDICAL ASSOCIATION, THE NATIONAL CATHOLIC BIOETHICS CENTER, ALABAMA PHYSICIANS FOR LIFE, NATIONAL ASSOCIATION OF PRO LIFE NURSES, AND NATIONAL ASSOCIATION OF CATHOLIC NURSES-U.S.A. IN SUPPORT OF PETITIONERS

OVIDE M. LAMONTAGNE
DENISE M. BURKE
MAILEE R. SMITH
*Counsel of Record*
ANNA R. PAPROCKI
MARY E. HARNED
AMERICANS UNITED FOR LIFE
655 15th St. NW, Suite 410
Washington, D.C. 20005
Telephone: 202-289-1478
Facsimile: 202-289-1473
Email: Mailee.Smith@AUL.org

COCKLE LEGAL BRIEFS (800) 225-6964
WWW.COCKLELEGALBRIEFS.COM

## TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ..... iii

STATEMENT OF INTEREST OF *AMICI CURIAE* ..... 1

SUMMARY OF ARGUMENT ..... 4

ARGUMENT ..... 6

I. It is Undisputed that a New Human Organism is Created at Fertilization ..... 6

II. Drugs and Devices Defined by the FDA as "Emergency Contraception" Have Post-Fertilization Mechanisms of Action ..... 9

A. Plan B can prevent implantation ..... 11

B. Ulipristal Acetate (*ella*) can prevent implantation or kill an implanted embryo ..... 12

C. Intrauterine Devices can also prevent implantation ..... 15

III. The Mandate Violates Sincerely Held Religious Beliefs and Freedom of Conscience ..... 16

A. HHS' "accommodation" for religious non-profits requires their compliance with the Mandate ..... 16

B. Freedom of Conscience is a fundamental right affirmed by our Founders ..... 19

TABLE OF CONTENTS – Continued

Page

C. Freedom of Conscience is a fundamental right affirmed by the U.S. Supreme Court ..... 23

D. Freedom of Conscience is a fundamental right affirmed by Congress ..... 26

CONCLUSION ..... 28

# TABLE OF AUTHORITIES

Page

CASES

*Association of American Physicians & Surgeons v. Mathews*, 423 U.S. 975 (1975) ..... 2

*Baird v. State Bar of Ariz.*, 401 U.S. 1 (1971) ..... 23

*Burwell v. Hobby Lobby*, 134 S. Ct. 2751 (2014) ..... 9, 10, 18, 19

*Cantwell v. Conn.*, 310 U.S. 296 (1940) ..... 23

*District of Columbia v. Heller*, 554 U.S. 570 (2008) ..... 2

*Planned Parenthood v. Casey*, 505 U.S. 833 (1992). ..... 24

*Roe v. Wade*, 410 U.S. 113 (1973). ..... 26

*Stenberg v. Carhart*, 530 U.S. 914 (2000) ..... 2

*Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503 (1969) ..... 23

*United States v. Seeger*, 380 U.S. 163 (1965) ..... 24, 25

*Welsh v. United States*, 398 U.S. 333 (1970) ..... 24, 25

*West Virginia State Board of Education v. Barnette*, 319 U.S. 624 (1943) ..... 23, 24

CONSTITUTIONAL PROVISION

U.S. CONST. amend. I ..... 19, 20, 23, 24

FEDERAL LAW AND REGULATIONS

42 U.S.C. §238n ..... 26

TABLE OF AUTHORITIES – Continued

Page

42 U.S.C. §300-7 ..... 26

42 U.S.C. §300a-7(b) ..... 27

42 U.S.C. §300a-7(c)(1) ..... 27

42 U.S.C. §300a-7(c)(2) ..... 27

42 U.S.C. §300a-7(d) ..... 27

42 U.S.C. §300a-7(e) ..... 27

42 U.S.C. §300gg-13 ..... 4

42 U.S.C. §1395w-22(j)(3)(B) ..... 27

48 C.F.R. §1609.7001(c)(7) ..... 27

78 Fed. Reg. 39870 ..... 16

78 Fed. Reg. 39874 ..... 16

78 Fed. Reg. 39876 ..... 16

78 Fed. Reg. 39877 ..... 17

78 Fed. Reg. 39878 ..... 16

78 Fed. Reg. 39881 ..... 17

79 Fed. Reg. 51092 ..... 18

Pub. L. No. 108-7, 117 Stat. 11, 126-27 (2000) ..... 27

Pub. L. No. 108-7, 117 Stat. 11, 472 (1999) ..... 26

Pub. L. No. 108-25, 117 Stat. 711, 733 (2003) ..... 27

Pub. L. No. 110-161, §508(d), 121 Stat. 1844, 2209 (2007) ..... 27

TABLE OF AUTHORITIES – Continued

Page

OTHER SOURCES

Adams, *A Declaration of the Rights of the Inhabitants of the Commonwealth of Massachusetts*, in REPORT FROM COMMITTEE BEFORE THE CONVENTION OF DELEGATES (1779) .....22

Berg, *Free Exercise of Religion*, in THE HERITAGE GUIDE TO THE CONSTITUTION (2005).....20

Condic, *When Does Human Life Begin? A Scientific Perspective* (The Westchester Institute for Ethics & the Human Person Oct. 2008), http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf.....6

Coy et al., *Roles of the oviduct in mammalian fertilization*, REPRODUCTION 144(6):649 (Oct. 1, 2012) .....7

Cushing, THE WRITINGS OF SAMUEL ADAMS (vol. II, 1906). .....22

Department of Health and Human Services, *Birth Control Methods* (updated Nov. 21, 2011), http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf .....15

Duramed Pharmaceuticals, *How Plan B One-Step Works* (2015), http://www.planbonestep.com/HowItWorks.aspx .....11

*ella* Labeling Information, http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.....13

TABLE OF AUTHORITIES – Continued

Page

European Medicines Agency, *Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone* (2009), http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf .....13

Food and Drug Administration, *Birth Control: Medicines To Help You* (updated Jan. 8, 2015), http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm.....5

Food and Drug Administration, *FDA's Decision Regarding Plan B: Questions and Answers* (updated Apr. 30, 2009), http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm .....11

Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of Conception and Pregnancy*, 9 NAT'L CATHOLIC BIOETHICS QUARTERLY 542 (2009) .....9, 12

George & Tollefsen, EMBRYO (2008) .....6

Glasier et al., *Ulipristal acetate versus levongestrel for emergency contraception: A randomized non-inferiority trial and meta-analysis*, 375 THE LANCET 555 (Jan. 2010).....13

Harrison & Mitroka, *Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health*, 45 ANNALS PHARMACOTHERAPY 115 (Jan. 2011).....12

TABLE OF AUTHORITIES – Continued

Page

Health Resources and Services Administration, *Women's Preventive Services Guidelines* (Aug. 1, 2011), http://www.hrsa.gov/womensguidelines/.....5

Jefferson, Letter to Edward Dowse, Esq. (Apr. 19, 1803).....22

Jefferson, Letter to New London Methodists (1809).....20

Jefferson, *Notes on Virginia* (1785).....20

Madison, *Memorial and Remonstrance Against Religious Assessments* ¶ 15 (1785).....21

Marcello et al., *Fertilization*, ADV. EXP. BIOL. 757:321 (2013).....7

Marsden et al., *Model systems for membrane fusion*, CHEM. SOC. REV. 40(3):1572 (Mar. 2011).....6

McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 HARV. L. REV. 1409 (1990).....20

Milton, THE QUOTABLE FOUNDING FATHERS: A TREASURY OF 2,500 WISE AND WITTY QUOTATIONS (2005).....21

Moore & Persaud, THE DEVELOPING HUMAN (7th ed. 2003).....8

National Institutes of Health, *Medline Plus Merriam-Webster Medical Dictionary* (2015), http://www.merriam-webster.com/medlineplus/fertilization.....8

Novak & Novak, WASHINGTON'S GOD (2006).....21

TABLE OF AUTHORITIES – Continued

Page

Okada et al., *A role for the elongator complex in zygotic paternal genome demethylation*, NATURE 463:554 (Jan. 28, 2010) ..... 7

Plan B Approved Labeling, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf. ..... 11

Raymond et al., *Embracing post-fertilisation methods of family planning: A call to action*, J. FAM. PLAN. REPROD. HEALTH CARE (2013) ..... 11

*Rights of Conscience Overview*, in DEFENDING LIFE 2013: DECONSTRUCTING ROE: ABORTION'S NEGATIVE IMPACT ON WOMEN (2013), http://www.aul.org/wp-content/uploads/2013/04/06-Freedom-of-Conscience.pdf ..... 27

Signorelli et al., *Kinases, phosphatases and proteases during sperm capacitation*, CELL TISSUE RES. 349(3):765 (Mar. 20, 2012) ..... 7

Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs (June 17, 2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf ..... 14

Trussell et al., *Emergency Contraception: A last chance to prevent unintended pregnancy* (Office of Population Research at Princeton University June 2010) ..... 10, 15

TABLE OF AUTHORITIES – Continued

Page

Trussell et al., *Emergency Contraception: A last chance to prevent unintended pregnancy* (Office of Population Research at Princeton University December 2013) ..... 14

Washington, Letter to the Religious Society Called Quakers (1789) ..... 22

## STATEMENT OF INTEREST OF *AMICI CURIAE*[1]

It is undisputed as a matter of science that a new, distinct human organism comes into existence during the process of fertilization – at the moment of sperm-egg fusion – and before implantation of the already-developing embryo into the uterine wall. Many drugs and devices labeled by the U.S. Food and Drug Administration as "emergency contraception," however, have post-fertilization (*i.e.*, life-ending) mechanisms of action which destroy the life of a human organism. In other words, these drugs and devices can work after a new human organism is created (at fertilization). Such "contraceptive" methods may prevent implantation and therefore "pregnancy," as defined by Respondents and their *amici*, but by preventing implantation these drugs and devices end the life of a unique human being.

*Amici curiae* are eight national organizations whose members include physicians, bioethicists, and other healthcare professionals who have a profound interest in protecting all stages of human life. *Amici* support a variety of public and private efforts that address healthcare affordability and accessibility, but

---

[1] Pursuant to this Court's Rule 37.2(a), the parties received at least ten-days' notice of the intent to file this brief. Written consent was obtained from the parties and is submitted with this brief. Pursuant to this Court's Rule 37.6, *Amici* state that no counsel for any party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of the brief.

oppose Respondents' requirement that private insurance plans cover drugs and devices with post-fertilization mechanisms of action. Cooperating with Respondents to arrange for and facilitate such coverage violates the sincere religious beliefs and freedom of conscience held by Petitioners and, therefore, to the extent that the government coerces their compliance and cooperation, that coercion is unlawful under the Religious Freedom Restoration Act (RFRA) and is unconstitutional.

*Amici* include the following medical and ethics associations:

**Association of American Physicians & Surgeons (AAPS)** is a national association of physicians. Founded in 1943, AAPS has been dedicated to the highest ethical standards of the Oath of Hippocrates and to preserving the sanctity of the patient-physician relationship. AAPS has been a litigant before this Court and in other appellate courts. *See, e.g.*, *Association of American Physicians & Surgeons v. Mathews*, 423 U.S. 975 (1975). In addition, this Court has specifically cited *amicus* briefs submitted by AAPS in high-profile cases. *See, e.g.*, *Stenberg v. Carhart*, 530 U.S. 914, 933 (2000); *id.* at 959, 963 (Kennedy, J., dissenting); *District of Columbia v. Heller*, 554 U.S. 570, 704 (2008) (Breyer, J., dissenting).

**American Association of Pro-Life Obstetricians & Gynecologists (AAPLOG)** is a non-profit professional medical organization consisting of approximately 2,500 obstetrician-gynecologist members and associates. AAPLOG held the title of "special interest group" within the American College of Obstetricians & Gynecologists (ACOG) for 40 years, from 1973 until 2013, until ACOG discontinued the designation of "special interest group."

**Christian Medical Association**, founded in 1931, is a non-profit national organization of Christian physicians and allied healthcare professionals with almost 14,000 members. It also has associate members from a number of allied health professions, including nurses and physician assistants.

**Catholic Medical Association** is a non-profit national organization comprised of over 2,000 members representing over 75 medical specialties.

**The National Catholic Bioethics Center**, established in 1972, conducts research, consultation, publishing, and education to promote human dignity in health care and the life sciences, and derives its message directly from the teachings of the Catholic Church.

**Alabama Physicians for Life (APFL)** is a non-profit medical organization that exists to draw attention to the issues of abortion and contraception. APFL encourages physicians to educate their patients regarding the innate value of human life at all stages

of development, as well as the risks inherent in abortion.

**National Association of Pro Life Nurses (NAPN)** is a national non-profit nurses' organization with members in every state. NAPN unites nurses who seek excellence in nursing for all and seeks to protect the ethical values of the nursing profession.

**National Association of Catholic Nurses-U.S.A.** is a national non-profit organization that gives nurses of different backgrounds the opportunity to promote Catholic moral principles in nursing and to stimulate desire for professional development.

Based on the destructive, post-fertilization effect of "emergency contraception" and the coercive, unconstitutional actions of Respondents requiring Petitioners to violate their religious beliefs and consciences, *Amici* urge this Court to reverse the lower court.

## SUMMARY OF ARGUMENT

The Affordable Care Act (ACA) requires that non-grandfathered private health insurance plans "provide coverage for and shall not impose any cost sharing requirements for . . . preventive care and screenings [for women]."[2] Respondents' regulatory mandate implementing this provision (the "Mandate")

[2] 42 U.S.C. §300gg-13.

requires these plans to fully cover, without co-pay, all drugs and devices labeled by the Food and Drug Administration (FDA) as "contraception."[3] It is scientifically undisputed that the life of a new human organism begins at fertilization. *See* Part I, *infra*. However, the FDA's definition of "contraception" includes drugs and devices with known post-fertilization (*i.e.*, life-ending) mechanisms of action.[4] *See* Part II, *infra*. Forcing employers to cooperate with Respondents in providing coverage of life-ending drugs and devices violates the conscientious beliefs of Petitioners and Americans across the nation.

Respondents exercised their discretion to create exemptions for churches and their integrated auxiliaries and conventions/associations. However, Respondents demand that certain religious non-profit employers, including Petitioners, which share the same religious objections as those churches that were granted exemptions, comply with the Mandate through a so-called "accommodation." *See* Part III.A., *infra*.

When the life-ending mechanisms of action of "emergency contraception" are understood, it is clear that, under this "accommodation," Respondents

---

[3] *See* Health Resources and Services Administration, *Women's Preventive Services Guidelines*, http://www.hrsa.gov/womensguidelines/. All internet sites visited August 11, 2015.

[4] *See* FDA, *Birth Control: Medicines To Help You* (updated Jan. 8, 2015), http://www.fda.gov/ForConsumers/ByAudience/ForWomen/FreePublications/ucm313215.htm.

effectively force Petitioners' cooperation in facilitating coverage for these drugs and devices in violation of their religious rights, contradicting this nation's long-standing commitment to the freedom of conscience. *See* Part III.B., C., and D., *infra*.

## ARGUMENT

### I. It is Undisputed that a New Human Organism is Created at Fertilization.

It is undisputed as a matter of science that a new, distinct human organism comes into existence during the process of fertilization, which begins at the time of sperm-egg fusion and before implantation.[5] Scientific literature is replete with statements regarding the beginning of human life:

- "The fusion of sperm and egg membranes ***initiates the life*** of a sexually reproducing organism."[6]
- "The ***life cycle of mammals begins*** when a sperm enters an egg."[7]

---

[5] *See, e.g.*, Condic, *When Does Human Life Begin? A Scientific Perspective* (The Westchester Institute for Ethics & the Human Person Oct. 2008), http://bdfund.org/wordpress/wp-content/uploads/2012/06/wi_whitepaper_life_print.pdf; George & Tollefsen, EMBRYO 39 (2008).

[6] Marsden et al., *Model systems for membrane fusion*, CHEM. SOC. REV. 40(3):1572 (Mar. 2011) (emphasis added).

- "Fertilization is the process by which male and female haploid gametes (sperm and egg) unite to produce ***a genetically distinct individual***."[8]

- "The oviduct or Fallopian tube is the anatomical region where ***every new life begins*** in mammalian species. After a long journey, the spermatozoa meet the oocyte in the specific site of the oviduct named ampulla, and fertilization takes place."[9]

- "Fertilization – ***the fusion of gametes to produce a new organism*** – is the culmination of a multitude of intricately regulated cellular processes."[10]

Respondents' own definition attests to the fact that human life begins at fertilization. According to the National Institutes of Health, "fertilization" is the "process of union of two gametes whereby the somatic chromosome number is restored *and the development*

---

[7] Okada et al., *A role for the elongator complex in zygotic paternal genome demethylation*, NATURE 463:554 (Jan. 28, 2010) (emphasis added).

[8] Signorelli et al., *Kinases, phosphatases and proteases during sperm capacitation*, CELL TISSUE RES. 349(3):765 (Mar. 20, 2012) (emphasis added).

[9] Coy et al., *Roles of the oviduct in mammalian fertilization*, REPRODUCTION 144(6):649 (Oct. 1, 2012) (emphasis added).

[10] Marcello et al., *Fertilization*, ADV. EXP. BIOL. 757:321 (2013) (emphasis added).

*of a **new individual** is initiated.*"[11] Further, one scientific textbook similarly explains the following:

> Human development begins at fertilization when a male gamete or sperm (spermatozoon) unites with a female gamete or oocyte (ovum) to produce a single cell – a zygote. This highly specialized, totipotent cell marked ***the beginning of each of us as a unique individual***.[12]

Thus, a new human organism is created *before* the developing embryo implants in the uterus – *i.e.*, before that time at which some people consider a woman "pregnant."

Respondents and their *amici* have at times tried to distract from Petitioners' objections to the Mandate by arguing over terminology concerning when "pregnancy" begins rather than when life begins (at fertilization). This semantic gamesmanship fails to respond to the concern that the objected-to drugs and devices can destroy human life after fertilization by blocking the implantation of a developing human embryo. Petitioners conscientiously oppose the voluntary ending of human life at any time following fertilization when such a termination is not necessary to save the life of the mother.

---

[11] NIH, *Medline Plus Merriam-Webster Medical Dictionary* (2015), http://www.merriam-webster.com/medlineplus/fertilization (emphasis added).

[12] Moore & Persaud, THE DEVELOPING HUMAN 16 (7th ed. 2003) (emphasis added).

## II. Drugs and Devices Defined by the FDA as "Emergency Contraception" Have Post-Fertilization Mechanisms of Action.

Drugs and devices with post-fertilization mechanisms of action are included in the FDA definition of "contraception," including "emergency contraception," even though these drugs and devices may end a developing, distinct human being's life by preventing implantation. For the FDA, the endpoint which defines a drug as a "contraceptive" is the ability to prevent a "pregnancy" – which in operational terms means preventing a positive pregnancy test ten days to two weeks after possible embryo formation. Thus, drugs and devices that interfere with *implantation*, which occurs days *after* fertilization and the creation of a new human organism, are categorized as "contraception."[13]

There is no dispute among the parties that at least some forms of "contraception" have post-fertilization mechanisms of action and can prevent implantation of an already-developing human embryo. For example, in *Burwell v. Hobby Lobby*, this Court noted:

---

[13] For an overview of how the definition of "pregnancy" has changed, *see* Gacek, *Conceiving Pregnancy: U.S. Medical Dictionaries and Their Definitions of Conception and Pregnancy*, 9 NAT'L CATHOLIC BIOETHICS QUARTERLY 542 (2009).

> [T]he [plaintiffs] have a sincere religious belief that life begins at conception. They therefore object on religious grounds to providing health insurance that covers methods of birth control that, as HHS acknowledges, may result in the destruction of an embryo.

134 S. Ct. 2751, 2775 (2014) (citation omitted).

This post-fertilization effect is further supported by Dr. James Trussell, who has appeared as an *amicus* supporting Respondents in numerous related cases.[14] In a study on "emergency contraception," he states: "To make an informed choice, women must know that [emergency contraception pills] . . . may at times inhibit implantation. . . ."[15] He has also stated that these post-fertilization effects "should certainly be [acknowledged and] celebrated, because without them the [contraceptive] method would not provide as

---

[14] For example, an *amicus* brief of Physicians for Reproductive Health, the American College of Obstetricians & Gynecologists, Dr. James Trussell, and other medical organizations and individuals has been filed in numerous cases. The brief contains semantic arguments, such as when "pregnancy" begins and whether a drug can be considered an "abortifacient." However, the relevant scientific benchmark is when the life of a human organism begins, which undisputedly occurs at fertilization.

[15] Trussell et al., *Emergency Contraception: A last chance to prevent unintended pegnancy* (Office of Population Research at Princeton University June 2010).

much benefit as they do."[16] In other words, if fertilization has occurred, the method provides "benefit" by preventing implantation.

Moreover, a drug classified by the FDA as "emergency contraception" – Ulipristal Acetate (*ella*) – can kill a human embryo *after* implantation. These post-fertilization mechanisms of action demonstrate that "emergency contraception" can end the life of an already-developing human organism.

### A. Plan B can prevent implantation.

The FDA approved labeling acknowledges that the "emergency contraception" drug known as Plan B can prevent implantation of an already-developing human embryo.[17] The FDA states on its website, "[i]f fertilization does occur, Plan B may prevent a fertilized egg from attaching to the womb (implantation)."[18] The same explanation is provided by Duramed Pharmaceuticals, the manufacturer of Plan B One-Step.[19]

---

[16] Raymond et al., *Embracing post-fertilisation methods of family planning: A call to action*, J. FAM. PLAN. REPROD. HEALTH CARE (2013).

[17] Plan B Approved Labeling, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2006/021045s011_Plan_B_PRNTLBL.pdf.

[18] FDA, *FDA's Decision Regarding Plan B: Questions and Answers* (updated Apr. 30, 2009), http://www.fda.gov/cder/drug/infopage/planB/planBQandA.htm.

[19] Duramed Pharmaceuticals, *How Plan B One-Step Works* (2015), http://www.planbonestep.com/HowItWorks.aspx (explaining

(Continued on following page)

Under Respondents' Mandate, Petitioners are forced to arrange for coverage of Plan B, despite its life-ending effect, in violation of Petitioners' genuinely held religious beliefs.

### B. Ulipristal Acetate (*ella*) can prevent implantation or kill an implanted embryo.

The chemical make-up of the "emergency contraception" drug Ulipristal Acetate (*ella*), unlike Plan B, is similar to the abortion drug RU-486. Like RU-486, *ella* is a selective progesterone receptor modulator (SPRM), and – "[t]he mechanism of action of ulipristal (*ella*) in human ovarian and endometrial tissue is identical to that of its parent compound mifepristone."[20] By blocking the progesterone – necessary to build and maintain the uterine wall during pregnancy – *ella* can either prevent a developing human embryo from implanting in the uterus, or it can kill an implanted embryo by essentially starving the embryo to death. Thus, regardless of whether "pregnancy" is defined as beginning at fertilization or at implantation, *ella* can abort a pregnancy.[21]

---

that Plan B can work by "[p]reventing attachment (implantation) to the uterus (womb)").

[20] Harrison & Mitroka, *Defining Reality: The Potential Role of Pharmacists in Assessing the Impact of Progesterone Receptor Modulators and Misoprostol in Reproductive Health*, 45 ANNALS PHARMACOTHERAPY 115 (Jan. 2011).

[21] *See* Gacek, *Conceiving Pregnancy*, *supra*.

Studies confirm that *ella* can harm an embryo.[22] The FDA-approved labeling notes that *ella* may "affect implantation"[23] and contraindicates use of *ella* if pregnancy is known or suspected. A study funded by *ella*'s manufacturer explains that SPRMs, "including ulipristal acetate," can "impair implantation."[24] While the study's researchers theorize that the dosage used in its trial "might be too low to inhibit implantation,"[25] they state affirmatively that "an additional postovulatory mechanism of action," *e.g.*, impairing implantation, "cannot be excluded."

---

[22] European Medicines Agency, *Evaluation of Medicines for Human Use: CHMP Assessment Report for Ellaone* 16 (2009), http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/001027/WC500023673.pdf.

[23] *ella* Labeling Information, http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022474s000lbl.pdf.

[24] Glasier et al., *Ulipristal acetate versus levongestrel for emergency contraception: A randomized non-inferiority trial and meta-analysis*, 375 THE LANCET 555 (Jan. 2010).

[25] In the Glasier study, "follow-up was done 5-7 days after expected menses. If menses had occurred and a pregnancy test was negative, participation [in the study] ended. If menses had not occurred, participants returned a week later." Considering that implantation must occur *before* menses, the study could not, and did not attempt to, measure an impact on an embryo prior to implantation or even shortly after implantation. Upon enrollment, participants were given a pregnancy test and pregnant women were excluded from the study. The only criterion for *ella* "working" was that a woman was not pregnant in the end. Whether that was achieved through blocking implantation or killing the embryo after implantation was not determinable.

Dr. Trussell's recent "emergency contraceptives" study further demonstrates *ella*'s potential to destroy a human embryo. An emergency contraceptive "could not be effective on average when started after 96 hours (four days) without a post-fertilization effect; the reason is that with increasing delay, a greater proportion of women would be too near to ovulation."[26] Significantly, Dr. Trussell's study notes that trials of *ella* showed no statistically significant reduced effectiveness for up to 120 hours or five days (the time frame studied).[27]

At the FDA advisory panel meeting for *ella*, Dr. Scott Emerson, a professor of Biostatistics at the University of Washington and a panelist, raised the point that the low pregnancy rate for women who take *ella* four or five days after intercourse suggests that the drug *must* have an "abortifacient" quality.[28]

Thus, contrary to their religious and conscientious beliefs, even with the "accommodation," Petitioners are required to arrange for coverage of *ella* –

---

[26] Trussell et al., *Emergency Contraception: A last chance to prevent unintended pregnancy* (Office of Population Research at Princeton University December 2013).

[27] *Id.*

[28] *See* Transcript, Food and Drug Administration Center for Drug Evaluation and Research (CDER), Advisory Committee for Reproductive Health Drugs (June 17, 2010), http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/ReproductiveHealthDrugsAdvisoryCommittee/UCM218560.pdf.

an abortion-inducing drug – under Respondents' Mandate.

### C. Intrauterine Devices can also prevent implantation.

Copper Intrauterine Devices (IUDs) are heavily promoted as another form of "emergency contraception" and can block the implantation of a human embryo after fertilization.[29] Dr. Trussell's study on "emergency contraceptives" concludes that "[i]ts very high effectiveness implies that emergency insertion of a copper IUD *must* be able to prevent pregnancy *after fertilization.*"[30] Put another way, IUDs are so effective *because* they do not just prevent conception – they can kill an already-developing human embryo.

Clearly, under Respondents' Mandate, Petitioners are required to arrange for coverage of devices that can kill human embryos, contrary to their religious and conscientious beliefs.

---

[29] *See* Department of Health and Human Services, *Birth Control Methods* (updated Nov. 21, 2011), http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf ("If fertilization does occur, the IUD keeps the fertilized egg from implanting in the lining of the uterus.").

[30] *See* Trussell et al., *Emergency Contraception* (2010), *supra* (emphasis added).

## III. The Mandate Violates Sincerely Held Religious Beliefs and Freedom of Conscience.

Petitioners have made clear their religious objections to paying or arranging for life-ending drugs and devices. The Mandate's coercive dichotomy – break the law or betray your religious beliefs – violates the U.S. Constitution's guarantee of freedom of conscience.

History, tradition, and jurisprudence affirm that a person cannot be forced to commit an act that is against his or her moral, religious, or conscientious beliefs – including payment for such an act – and this history, tradition, and jurisprudence unequivocally support the Petitioners.

### A. HHS' "accommodation" for religious non-profits requires their compliance with the Mandate.

HHS' own explanation of how the "accommodation" works contradicts its claim that the "accommodated" religious groups "would not contract, arrange, pay, or refer for [the coverage that violates their religious beliefs]." 78 Fed. Reg. 39870, 39878 (2013). The July 2013 final rule clarifies that plan participants and beneficiaries on an accommodated plan do *not* have "two separate health insurance policies." *Id.* at 39876. Rather, the insurance issuer (or third-party administrator (TPA) for self-insured plans) will make what HHS calls "separate payments" for the objectionable coverage. *Id.* at 39874. The same is true for

church plans, except that the government will seek to induce the administrators for these ERISA-exempt plans to comply with its rules.

These payments are directly linked to the insurance plan from which they are supposedly separate. There are no opt-in or opt-out provisions. Payments are automatically made for the "accommodated" plan's participants and beneficiaries and start and end with a person's enrollment in the "accommodated" plan. HHS acknowledges that "issuers typically do not receive enrollee information prior to enrollment." *Id.* at 39881. The relationship between the issuer or TPA making the "separate payments" and the plan enrollees is completely dependent on and related to the supposedly "accommodated" organization's plan.

The July 2013 final rule explained that these payments can be envisioned as "cost neutral" for the insurance issuer "because they would be insuring the same set of individuals under both the group health insurance policies and [the separate payments]." *Id.* at 39877. Even accepting HHS' assumption that providing coverage of contraceptives (use of which is already ubiquitous) without co-pays would result in fewer pregnancies and at least equally lower costs on the "accommodated" group health plan, the math only works if these contraceptive payments are considered in conjunction with the supposedly separate health plan provided by the religious employer.

Under the interim final rule issued in August 2014, the so-called "accommodation" operates exactly the same. HHS explains the change as simply "provid[ing] an alternative process" for "notice of . . . religious objections." 79 Fed. Reg. 51092. That "alternative process" requires handing over the name and contact information "for any of the plan's third party administrators and health insurance issuers." *Id.* at 51098. HHS explains that it will use that information to force the religious employer's health insurance issuer to include the objected-to items and services, or, in the case of a church plan, induce its TPA to do the same. *Id.* The coercive impact on the plan paid and arranged for by the religious employer remains the same and renders the religious employer complicit with arranging coverage for life-ending drugs and devices.

The "accommodation" effectively requires a religious non-profit's cooperation in the arranging and facilitating coverage for the drugs and devices to which it objects. Thus, it substantially burdens religious beliefs in a manner similar to that of the plaintiffs in *Burwell v. Hobby Lobby*. Importantly, this Court held that "[b]y requiring [plaintiffs] and their companies to arrange for such coverage, the HHS mandate demands that they engage in conduct that seriously violates their religious beliefs." *Hobby Lobby*, 134 S. Ct. at 2775.

Notably, HHS has expressly exempted churches and their auxiliaries that have objections similar to those of Petitioners from compliance with the Mandate.

Concurring in *Hobby Lobby*, Justice Kennedy noted that the Religious Freedom Restoration Act "is inconsistent with the insistence of an agency such as HHS on distinguishing between different religious believers – burdening one while accommodating the other – when it may treat them both equally by offering both of them the same accommodation." *Id.* at 2786 (Kennedy, J., concurring).

Ultimately, it is for Petitioners to determine whether what HHS has styled as an "accommodation" burdens their religious beliefs. This Court squarely addressed this point in *Hobby Lobby*, holding that Petitioners "sincerely believe that providing the insurance coverage demanded by the HHS regulations lies on the forbidden side of the line, and it is not for us to say that their religious beliefs are mistaken or insubstantial." *Id.* at 2779. Here, as in *Hobby Lobby*, it is not for Respondents or the courts to determine what "lies on the forbidden side of the line" for Petitioners' religious beliefs regarding complicity with life-ending drugs and devices.

### B. Freedom of Conscience is a fundamental right affirmed by our Founders.

The First Amendment guarantees that Congress shall make no law prohibiting the free exercise of religion. U.S. CONST. amend. I. The very root of that

promise is that the government cannot force a person to commit an act in violation of his or her religion.[31]

The signers to the religion provisions of the First Amendment were united in a desire to protect the "liberty of conscience."[32] Thomas Jefferson was clear that freedom of conscience is not to be subordinate to the government:

> [O]ur rulers can have authority over such natural rights only as we have submitted to them. The rights of conscience we never submitted, we could not submit. We are answerable for them to our God.[33]

Jefferson also stated that no provision in the Constitution "ought to be dearer to man than that which protects the rights of conscience against the enterprises of civil authority."[34]

Likewise, James Madison, considered the Father of the Bill of Rights, was deeply concerned that the freedom of conscience be protected. Madison stated:

> The Religion then of every man must be left to the conviction and conscience of every

---

[31] *See generally* McConnell, *The Origins and Historical Understanding of Free Exercise of Religion*, 103 HARV. L. REV. 1409 (1990).

[32] The Founders often used the terms "conscience" and "religion" synonymously. Berg, *Free Exercise of Religion*, in THE HERITAGE GUIDE TO THE CONSTITUTION 310 (2005).

[33] Jefferson, *Notes on Virginia* (1785).

[34] Jefferson, Letter to New London Methodists (1809).

> man; and it is the right of every man to exercise it as these may dictate. This right is in its nature *an unalienable right*.[35]

Madison described the conscience as "the most sacred of all property."[36]

Madison understood that if man cannot be loyal to his conscience, then a government cannot expect him to be loyal to less compelling obligations. If the government demands that he betray his conscience, the government has eliminated the only moral basis for obeying any law.

George Washington maintained that "the establishment of Civil and Religious Liberty was the Motive that induced me to the field of battle."[37] Washington advised that the law should always extensively accommodate conscience:

> The conscientious scruples of all men should be treated with great delicacy and tenderness: and it is my wish and desire, that the laws may always be extensively accommodated to them, as a due regard for the protection

---

[35] Madison, *Memorial and Remonstrance Against Religious Assessments* ¶ 15 (1785) (emphasis added).

[36] Milton, THE QUOTABLE FOUNDING FATHERS: A TREASURY OF 2,500 WISE AND WITTY QUOTATIONS 36-37 (2005).

[37] Novak & Novak, WASHINGTON'S GOD 111 (2006); Milton, *supra*.

> and essential interests of the nation may justify and permit.[38]

John Adams stated that "no subject shall be hurt, molested, or restrained, in his person, liberty, or estate, for worshipping God in the manner most agreeable to the dictates of his own conscience."[39] Patriot leader Samuel Adams wrote that the liberty of conscience is an original right.[40]

Forcing Petitioners to arrange for and facilitate coverage for life-ending drugs and devices to which they are conscientiously opposed eviscerates one of the very purposes for which this Nation was formed. As Thomas Jefferson charged us:

> [W]e are bound, you, I, every one, to make common cause, even with error itself, to maintain the common right of freedom of conscience. *We ought with one heart and one hand hew down the daring and dangerous efforts of those who would seduce the public opinion to substitute itself into . . . tyranny over religious faith. . . .*[41]

---

[38] Washington, Letter to the Religious Society Called Quakers (1789).

[39] Adams, *A Declaration of the Rights of the Inhabitants of the Commonwealth of Massachusetts*, in REPORT FROM COMMITTEE BEFORE THE CONVENTION OF DELEGATES (1779).

[40] Cushing, THE WRITINGS OF SAMUEL ADAMS 350-59 (vol. II, 1906).

[41] Jefferson, Letter to Edward Dowse, Esq. (Apr. 19, 1803) (emphasis added).

### C. Freedom of Conscience is a fundamental right affirmed by the U.S. Supreme Court.

"Freedom of conscience" is referenced explicitly throughout Supreme Court jurisprudence. *See, e.g.*, *Baird v. State Bar of Ariz.*, 401 U.S. 1, 6 (1971) ("This conjunction of liberties is not peculiar to religious activity and institutions alone. The First Amendment gives freedom of mind the same security as freedom of conscience."); *Tinker v. Des Moines Indep. Cmty. Sch. Dist.*, 393 U.S. 503, 506 n.2 (1969) (referencing "constitutionally protected freedom of conscience").

This Court has stated that *"[f]reedom of conscience . . . cannot be restricted by law."* *Cantwell v. Conn.*, 310 U.S. 296, 303 (1940) (emphasis added). While the "freedom to believe" is absolute, the "freedom to act" is not; however, "in every case," regulations on the freedom to act cannot "unduly infringe the protected freedom." *Id.* at 303-04.

In the 1940s, the Court considered regulations requiring public school students to recite the pledge to the American flag, ultimately vindicating the students' freedom of conscience. In *West Virginia State Board of Education v. Barnette*, the Court stated:

> If there is any fixed star in our constitutional constellation, it is that no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion or force citizens to confess by

> word or act their faith therein. . . . [L]ocal authorities [may not] transcend [ ] constitutional limitations on their power and invade[ ] the sphere of intellect and spirit which it is the purpose of the *First Amendment to our Constitution* to reserve from all official control.

*Barnette*, 319 U.S. 624, 642 (1943) (emphasis in original). The Court also stated, "[F]reedom to differ is not limited to things that do not matter much. . . . The test of its substance is the right to differ as to things that touch the heart of the existing order." *Id.* Based upon these principles, the Court ruled it unconstitutional to force public school children to perform an act that was against their religious beliefs.[42]

The Court has also protected men who were conscientiously opposed to war. In *United States v. Seeger* and *Welsh v. United States*, the Court extended draft exemptions[43] to "all those whose consciences, spurred by deeply held moral, ethical, or religious beliefs, would give them no rest or peace if they

---

[42] *Barnette* has been affirmed on numerous occasions. *See, e.g., Planned Parenthood v. Casey*, 505 U.S. 833 (1992).

[43] Section 6(j) of the Universal Military Training and Service Act exempted men from the draft who were conscientiously opposed to military service because of "religious training and belief." Early colonial charters and state constitutions similarly spoke of freedom of conscience as a right, and during the Revolutionary War, many states granted exemptions from conscription to Quakers, Mennonites, and others with religious beliefs against war.

allowed themselves to become part of an instrument of war." *Welsh*, 398 U.S. 333, 344 (1970) (affirming *Seeger*, 380 U.S. 163 (1965)).

*Welsh* acknowledged that §6(j) protected persons with "intensely personal" convictions – even when other persons found those convictions "incomprehensible" or "incorrect." *Welsh*, 398 U.S. at 339. Seeger and Welsh "held deep conscientious scruples against taking part in wars where people were killed. Both strongly believed that killing in war was wrong, unethical, and immoral, and their consciences forbade them to take part in such an evil practice." *Id.* at 337. Important here is Welsh's statement:

> I believe that human life is valuable in and of itself; in its living; therefore I will not injure or kill another human being. . . . I cannot, therefore conscientiously comply with the Government's insistence that I assume duties which I feel are immoral and totally repugnant.

*Id.* at 343.

The holdings in these cases demonstrate a strong commitment by this Court to protect freedom of conscience. Like Welsh, Petitioners believe that human life is valuable – at all stages and in all situations. Being forced to arrange for drugs and devices that terminate a human life is just as objectionable as being forced to participate in the termination of human life in war.

### D. Freedom of Conscience is a fundamental right affirmed by Congress.

Congress has passed numerous measures expressing American commitment to protecting the freedom of conscience. Congress passed the first of the Church Amendments following this Court's decision in *Roe v. Wade*, 410 U.S. 113 (1973).[44] The original and subsequent Church Amendments protect healthcare providers from discrimination by recipients of HHS funds on the basis of their objection, because of religious belief or moral conviction, to performing or participating in not only abortion but *any* lawful health service or research activity.

In 1996, the Coats Amendment was enacted to prohibit the federal government and state or local governments that receive federal financial assistance from discriminating against individual and institutional healthcare providers, including participants in medical training programs, who refused to, among other things, receive training in abortions, require or provide such training, perform abortions, or provide referrals or make arrangements for such training or abortions.[45]

In 1999, Congress prohibited health plans participating in the federal employees' benefits program from discriminating against individuals who refuse to prescribe contraceptives.[46] Similarly, in 2000, Congress

---

[44] 42 U.S.C. §300-7.

[45] 42 U.S.C. §238n.

[46] *See* Pub. L. No. 108-7, 117 Stat. 11, 472 (1999).

passed a law requiring the District of Columbia to include a conscience clause protecting religious beliefs and moral convictions in any contraceptive mandate.[47]

The Hyde-Weldon Amendment, first enacted in 2005, provides that no federal, state, or local government agency or program that receives funds under the Labor, Health and Human Services (LHHS) appropriations bill may discriminate against a healthcare provider because the provider refuses to provide, pay for, provide coverage of, or refer for abortion.[48] The Amendment is subject to annual renewal and has survived multiple challenges.[49]

Respondents' Mandate ignores the long-standing national commitment to protect the freedom of conscience.[50]

---

[47] *See* Pub. L. No. 108-7, 117 Stat. 11, 126-27 (2000).

[48] Pub. L. No. 110-161, §508(d), 121 Stat. 1844, 2209 (2007).

[49] Many similar conscience provisions related to federal funding have been passed over the last 45 years. *See, e.g.*, 42 U.S.C. §1395w-22(j)(3)(B) (1997); 42 U.S.C. §300a-7(e) (1979); 42 U.S.C. §300a-7(c)(2), (d) (1974); 42 U.S.C. §300a-7(b), (c)(1) (1973); 48 C.F.R. §1609.7001(c)(7) (1998); Pub. L. No. 108-25, 117 Stat. 711, 733 (2003).

[50] Respondents' actions also contravene the laws and clear intent of the vast majority of states. *See Rights of Conscience Overview*, in DEFENDING LIFE 2013: DECONSTRUCTING ROE: ABORTION'S NEGATIVE IMPACT ON WOMEN (2013), http://www.aul.org/wp-content/uploads/2013/04/06-Freedom-of-Conscience.pdf.

## CONCLUSION

It is undisputed as a matter of science that a new human organism is created at fertilization. Being forced to arrange and facilitate coverage for drugs and devices that can end a human life after fertilization amounts to forced participation in the act of ending that life. Respondents' Mandate and its purported accommodation which requires Petitioners to cooperate in the provision of such drugs and devices comprise a coercive policy which runs contrary to the history, tradition, and jurisprudence of this Nation, violates Petitioners' freedom of conscience, and is, therefore, unconstitutional.

This Court should grant the petition and reverse the lower court.

Respectfully submitted,

OVIDE M. LAMONTAGNE
DENISE M. BURKE
MAILEE R. SMITH
*Counsel of Record*
ANNA R. PAPROCKI
MARY E. HARNED
AMERICANS UNITED FOR LIFE
655 15th St. NW, Suite 410
Washington, D.C. 20005
Telephone: 202-289-1478
Facsimile: 202-289-1473
Email: Mailee.Smith@AUL.org